

**Notice of Allowability**

Application No.

09/015,399

Applicant(s)

HINKKANEN, ARI

Examiner

Art Unit

G. R. Ewoldt, Ph.D.

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/05/03.
2. ☒ The allowed claim(s) is/are 1-3, 5-10, 17, 18, 20, 23, 24, 27, 28.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 6 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____    |
| 3 <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. _____  | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment         |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|  | 9 <input type="checkbox"/> Other   |

11/20/03  
G.R. EWOLDT, PH.D.  
PRIMARY EXAMINER

**EXAMINER'S AMENDMENT**

3. The drawing, filed 8/05/03, has been found acceptable.
2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
3. Authorization for this examiner's amendment was given in a telephone interview with Patrick Skacel on 11/20/03.

IN THE SPECIFICATION:

4. On page 22, the Abstract has been changed to --The invention relates to a fusion protein having epitopes of at least two of the autoantigens glutamic acid decarboxylase (GAD65), islet cell antigen (IA2) and preproinsulin (PPINS) wherein said epitopes are connected with a linker peptide. The fusion protein must be able to bind to a solid phase. The invention also concerns the cDNA, and a vector and cell comprising said cDNA. Furthermore, this invention relates to the use of said fusion protein in an immunoassay for the simultaneous detection of autoantibodies related to insulin-dependent diabetes mellitus.--.

IN THE CLAIMS:

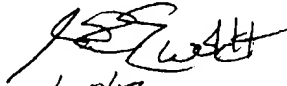
5. Claim 3, has been changed to --3. (Previously amended) The fusion protein according to claim 2 wherein the epitope of IA2 comprises amino acids 771-979 of SEQ ID NO:5, the epitope of GAD65 comprises amino acids 102-585 of SEQ ID NO:6, and the epitope of PPINS comprises amino acids 1-110 of SEQ ID NO:7.--.
6. Claim 5, has been changed to --5. (Currently Amended) The fusion protein according to claim 1, wherein said linker peptide is provided with a member of an affinity binding pair.--.
7. Claim 23, has been changed to --23. (Currently amended) The fusion protein of claim 1 wherein said linker peptide is labeled with a member of an affinity binding pair.--.
8. Claim 27, has been changed to --27. (Currently amended) The fusion protein of claim 18 wherein said linker peptide is labeled with a member of an affinity binding pair.--.
9. In Claim 10, "encompassing" has been changed to --comprising--.

Serial No. 09/015,399  
Art Unit 1644

3

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

G.R. Ewoldt, Ph.D.  
Primary Examiner  
Technology Center 1600  
November 24, 2003

  
11/20/03  
**G.R. EWOLDT, PH.D.**  
**PRIMARY EXAMINER**